Remarks

Claims 48 and 69-71 are pending in this application. Claims 52, 54, and 61 are canceled without prejudice to Applicants' right to pursue the subject matter recited by them in one or more divisional, continuation, or continuation-in-part applications.

Claim 48 is amended to recite, in part, a solid pharmaceutical composition for the treatment of allergic rhinitis or urticaria comprising about 0.1 mg to 5 mg of descarboethoxyloratadine ("DCL"), which is suitable for oral administration. The support for the additional limitations can be found, for example, on page 16, lines 1-9 of the specification. Claim 71 is amended to correct its dependency. No new matter has been introduced.

Applicants respectfully submit that all of the pending claims are allowable for at least the following reasons.

A. The Rejection Under 35 U.S.C. § 112 Should Be Withdrawn

On page 2 of the Office Action, claim 48 is rejected as allegedly indefinite. In particular, it is alleged that the claims is indefinite based on the Examiner's assertion that the term "for the treatment of allergic rhinitis and urticaria" fails to further limit the scope of the claim, and is irrelevant. Applicants respectfully disagree.

First, Applicants respectfully disagree with the Examiner's allegation that this term fails to further limit the scope of the claims because those of ordinary skill in the art would understand that the term does further limit the scope of the claim, *e.g.*, to compositions using amounts useful for urticaria or allergic rhinitis.

More important, however, is the fact that, even assuming that the term does not further limit the scope of the claim, the term is merely an unambiguous part of the preamble, and thus the claim is still not indefinite. In other words, although the term "for the treatment of allergic rhinitis and urticaria" may be superfluous, it does not render the claim indefinite. This is because "those of ordinary skill in the art would understand what is claimed when [claim 48] is read in light of the specification." *Orthokinetics, Inc. v. Safety Travel Chairs, Inc.*, 806 F.2d 1565, 1576 (Fed. Cir. 1986). Consequently, Applicants respectfully request that the rejection of claim 48 under 35 U.S.C. § 112, ¶2 be withdrawn.

B. The Rejection Under Non-Statutory Double Patenting

On pages 2-3 of the Office Action, claims 48 and 69-70 are rejected under the judicially-created obviousness type double patenting over claims 48-57 of co-pending application no. 10/989,514. Without addressing the merits of this rejection, Applicants respectfully request that this rejection be held in abeyance until the scope of allowable subject matter in this application becomes clear. Applicants will either file a terminal disclaimer or cancel the cited claims at an appropriate time, if necessary.

C. The Rejection Under 35 U.S.C. § 102 Should Be Withdrawn

On pages 3-4 of the Office Action, claims 48 and 69-70 are rejected as allegedly anticipated by U.S. Patent No. 4,659,716 to Villani *et al.* ("Villani") for the reasons stated in the Office Action. Applicants respectfully disagree.

It is well-settled that "[a] claim is anticipated only if each and every element as set for the in the claim is found, either expressly or inherently described, in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631 (Fed. Cir. 1987). Applicants respectfully point out that the claims are not anticipated because Villani fails to disclose "each and every element" of the claims.

Claim 48 recites, in part, a solid pharmaceutical composition comprising 0.1 to 5 mg of DCL, which is suitable for oral administration. Villani does not disclose the claimed composition. Villani discloses a genus of compounds which encompasses DCL, although Applicants note that DCL is disclosed as an example. Furthermore, Villani discloses a very broad range of amount of active ingredient, *i.e.*, 1-1000 mg, that can purportedly be used in the compositions it discloses. Therefore, Villani discloses a composition containing 1-1000 mg of DCL.[1] Furthermore, the compositions of DCL disclosed in Villani, *i.e.*, those disclosed in Examples E-I of Villani, respectively contain: 200mg/g; 200mg/g; 200 mg/g; 200mg/g; and 100 mg/g of DCL. These amounts are significantly different than the amounts recited by the pending claims.

In view of the broad range and much higher amounts of DCL, the compositions disclosed in Villani are clearly different from a solid pharmaceutical composition comprising 0.1 to 5 mg of DCL, suitable for oral administration. *See In re Meyer*, 599

[1] Applicants respectfully point out that Villani even falls short of disclosing such a composition. This is because, while DCL is disclosed as an exemplary compound, Villani makes it clear that its preferred compound is not DCL. *See* Villani, column 11, lines 21-23.

F.2d 1026 (C.C.P.A. 1979) (holding that claim to a species is not anticipated by a prior are reference disclosing a genus because the prior art embraced a large number of species.). *See also generally, In re Peterson*, 315 F.3d 1325 (Fed. Cir. 2003), where a claim to a super-alloy containing about 1-3% rhenium and about 14% chromium was rejected under 35 U.S.C. § 103 over a reference that discloses a similar super-alloy containing 0-7% rhenium and 3-18% chromium, but no rejection under 35 U.S.C. § 102 was made. Consequently, Applicants respectfully request that the rejection of the claims under 35 U.S.C. § 102 be withdrawn.

D. The Rejection Under 35 U.S.C. § 103 is Obviated

On pages 4-5 of the Office Action, claims 54 and 61 are rejected as allegedly obvious over Villani in view of Berkow *et al.*, *The Merck Manual of Diagnosis and Therapy*, 16th Ed., pp 326-332 (1992). Although Applicants respectfully disagree, the rejection is obviated in view of the cancellation of claims 54 and 61. Thus, Applicants respectfully request that the rejection under 35 U.S.C. § 103 be withdrawn.

Conclusion

For at least the foregoing reasons, Applicants respectfully submit all of the pending claims are allowable, and thus respectfully request the allowance thereof.

No fee is believed due for this submission. Should any additional fees be required for this submission or to avoid abandonment of the application, please charge such fees to Jones Day Deposit Account No. 503013.

Respectfully submitted,

Date November 28, 2005

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